

Original Research Article

A comparative study of Lichtenstein tension free hernioplasty with prolene hernia system hernioplasty for inguinal hernia

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ABSTRACT

Background: Lichtenstein tension-free hernioplasty (LTH) has become the gold standard for hernia repair. It is easy to learn and perform with minimal complications and low recurrence rate. But it deals with only superior half of the myopectineal orifice. Prolene hernia system (PHS) hernioplasty is safe, causes minimal pain and has minimal recurrence rate but is still not popular due to high cost. The aim of the study is to compare the Lichtenstein tension-free hernioplasty with hernioplasty using prolene hernia system.

Methods: A total of 60 patients with inguinal hernia were equally grouped into cases (PHS) and controls (LTH). Outcome measures were compared with regards to postoperative pain, hospital stay and complications.

Results: There was no significant difference in mean days of post-operative hospital stay among cases and controls. On post-operative days 1 and 3, most of the patients experienced moderate pain and by 8th post-operative day most of the patients had no pain. The pain intensity decreased with increase in post-operative days. Seroma formation was seen among 2 (6.67%) cases (PHS) group in comparison to 3 (10.0%) controls (Lichtenstein) group. Post-operative wound infection was seen among 1 (3.33%) cases (PHS) group and controls (Lichtenstein) group each. Recurrence was seen neither among patients treated with either technique.

Conclusions: Prolene Hernia System mesh repair could be a suitable alternative to time honored Lichtenstein hernia repair with added advantage of strengthening the whole of myopectineal orifice, and virtually eliminating any risk of recurrence.

Keywords: Inguinal hernia, Prolene hernia system, Lichtenstein hernia repair, Outcome

INTRODUCTION

Inguinal hernia repair is one of the most commonly performed surgeries in the world.¹ There are numerous hernia repair procedures using different surgical approaches, the most important criteria for the choice of method are safety, recurrence rate and satisfaction to the patient.

Lichtenstein tension-free hernioplasty (LTH) has become the gold standard for hernia repair.² LTH is easy to learn and perform with minimal complications and low

recurrence rate. It is suitable for outpatient surgery using local anesthesia. But the major drawback is that it deals with only superior half of the myopectineal orifice (MPO).³

The prolene hernia system (PHS) is a bilayer patch device.⁴ It has three-dimensional configuration. It consists of the 'onlay' patch and the 'underlay' patch. The 'onlay' patch covers the inguinal defect, the connector acts like a plug and underlay patch covers the entire myopectineal orifice, which contains the indirect and direct inguinal hernia space and femoral triangle,

thus providing effective complete coverage of MPO. PHS hernioplasty is safe, causes minimal pain and has minimal recurrence rate but is still not popular due to high cost.⁵ With this background, this study was aimed to compare the LTH with hernioplasty using PHS.

METHODS

This prospective interventional study was conducted over a period of two years on adult patients with inguinal hernia. The study was approved by Institutional ethics committee before the beginning of the study.

Study design

A randomised case control design was used. The first patients were allotted to either group by a lottery method and subsequently patients were allotted alternatively.

Place of study: The study was carried out in Padmashree Dr. D.Y. Patil Hospital and Research Centre, Pimpri, Pune.

Period of study: The duration of study was three years from September 2015 to September 2018.

Sample size

Sample size was calculated by using Open Epi software (CDC Atlanta, USA) using following formula:

$$n(\text{size per group}) = 2c/\delta^2 + 1$$

where $\delta = (l\mu_1 - \mu_2l)/\sigma^2 + 1$ is the standard effective size.

For a two-sided test of 5%, μ_1 and μ_2 are the outcome measure of the two treatment groups, σ is the common standard deviation and $c=7.9$ for 80% power. Taking this formula, the minimum required sample size was 30 for each group.

So, sample size taken was:

Controls- Patients undergoing LTH (n=30).

Cases- Patients undergoing PHS (n=30).

Inclusion criteria

Cases with inguinal hernia and above 18 years were included in the study.

Exclusion criteria

Patients less than 18 years of age with complicated and recurrent inguinal hernia were excluded from the study.

Detailed clinical history was taken and general physical examination was done. All routine laboratory

investigations including USG B/L inguino-scrotal region (if required) were done. All cases were operated under spinal, epidural or general anaesthesia and followed on day 1, 3, 5, 7 and 30 for postoperative complications. Occurrence of late complications were looked for during follow up at 3, 6, 12 and 18 months.

Statistical analysis

All collected information was entered in excel sheet and was analysed using epi-info software. For qualitative variable Chi-square was used to calculate statistical significance. Unpaired student t-test and ANOVA test were used to assess statistical significance between continuous variables.

RESULTS

The mean age of cases was 49.11±14.21 years and of controls was 48.23±15.74 years (p value 0.8209). Most of the cases and controls were male. There was no difference in distribution of gender among cases and controls. Out of total 37 right sided inguinal hernia patients, 18 patients were repaired with PHS and 19 patients were treated with LTH. Out of total 23 left sided inguinal hernia patients, 12 patients were repaired with PHS and 11 patients were treated with LTH. There was no significant difference among subcategories of right and left sided inguinal hernia and methods of repair. (p value 0.2650 and 0.7844 respectively) (Table 1).

Table 1: Comparison of patient characteristics between the two groups.

Patient Characteristics	Cases	Controls	P value
No. of patients	30	30	--
Mean age	49.11	48.23	0.8209#
±SD	±14.21	±15.74	
Male/female	28/2	28/2	<0.001
Right indirect	10	13	0.227
Right direct	07	03	
Right pantaloon	01	03	
Left indirect	04	04	0.692
Left direct	04	05	
Left pantaloon	04	02	

Verbal rating scale for pain was used to compare between cases and controls in our study. On day 1, severe pain was observed in 4 (33.33%) cases in comparison to 3 (10%) controls. Most of patients felt moderate pain in both the study groups. (Cases-73.33% and Controls-66.67%). On day 3, severe pain was observed in 3 (10.0%) cases in comparison to 2 (6.67%) controls. Most of patients felt moderate pain in both the study groups. (Cases-63.33% and controls-50.0%). On day 8, severe pain was observed in none of the participants. Most of patients felt no pain in both the study groups (Table 2).

Table 2: Comparison of post-operative pain among cases and controls.

Post-operative day	Post-operative pain	Cases	%	Controls	%	Total	%
Day 1	Mild	4	13.33	7	23.33	11	18.33
	Moderate	22	73.33	20	66.67	42	70.00
	Severe	4	13.33	3	10.00	7	11.67
Day 3	None	3	10.00	6	20.00	9	15.00
	Mild	5	16.67	7	23.33	12	20.00
	Moderate	19	63.33	15	50.00	34	56.67
	Severe	3	10.00	2	6.67	5	8.33
Day 8	None	13	43.33	14	46.67	27	45.00
	Mild	11	36.67	9	30.00	20	33.33
	Moderate	6	20.00	7	23.33	13	21.67
	Severe	0	0.00	0	0.00	0	0.00
Day 1 vs. day 3*		0.8537		0.8822		0.6754	
Day 1 vs. day 8*		<0.001		0.0156		0.0012	
Day 3 vs. day 8*		0.0058		0.0497		0.0324	

*By Wilcoxon matched pairs test.

Mean duration of surgery among cases was 45.87±7.03 minutes while it was 46.31±6.78 minutes among controls. Total duration of surgery was 31-40 minutes among 10 cases and 9 controls in our study. Total duration of surgery was 41-50 minutes among 17 cases and 16 controls. Total duration of surgery was 51-60 minutes among 3 cases and 5 controls. There was no significant difference among duration of surgery among cases and controls (p value 0.1564).

Mean post-operative hospital stay among cases was 3.73±1.21 days while it was 4.22±2.03 days among controls. There was no significant difference in mean days of post-operative hospital stay among cases and controls (p value 0.2608)

Seroma formation was seen among 2 (6.67%) cases in comparison to 3 (10.0%) controls. Post-operative wound infection was seen among 1 (3.33%) cases and controls each. Chronic groin pain was seen among 2 (6.67%) cases and 3 (10.0%) controls (Table 3).

Table 3: Comparison of outcome measures between the two groups.

Outcome measure	Cases	Controls	P value
Mean duration of surgery	45.87 ±7.03	46.31 ±6.78	0.1564
Mean hospital stay	3.73 ±1.21	4.22 ±2.03	0.2608
Seroma formation	02	03	0.644
Wound infection	01	01	0.4720
Chronic groin pain	02	03	0.644
Recurrences	00	00	--

DISCUSSION

Lichtensteins mesh repair is the time tested procedure for hernia repair since 25 years and is considered 'the gold-

standard' procedure. PHS mesh is a newer type of mesh which completely strengthens the myopectineal orifice, the weakness of which is the causative factor for both inguinal and femoral hernias, and thereby giving better protection.

In our study, the duration of surgery was marginally high in the PHS group probably because of the extra time needed for the dissection and placement of underlay patch. Karaca et al and Badkur et al, found significant difference between both groups with a p value of <0.05, the PHS mesh repair taking longer time compared to LTH.^{3,6} Whereas, Sanjay et al, found no significant difference between the two types of repair in operation time.⁷ As known, duration of surgery depends on many factors like surgeon's experience, obesity, techniques used etc. Hence, various studies report different durations. In our study, duration of surgery was consistent with the literature.

There was no significant difference in mean days of post-operative hospital stay among cases and controls (p value 0.2608). Karaca et al, Sanjay et al observed that there was no significant difference between PHS and Lichtenstein group in terms of hospital stay.^{6,7} However, Badkur et al in their study observed that the mean duration of post-operative hospital stay for the PHS group and Lichtenstein group was statistically significant.³ Duration of hospital stay depends on many factors like, patient's preferences, surgeon's preferences, availability of hospitals nearby, etc.

In the past, post-operative pain following tension repairs was an important and a frequently encountered problem. Once the tension-free mesh repairs were introduced, its incidence has decreased. There was no significant difference in post-operative pain at day 1, 3 and 8 among cases and controls. There was significant difference in pain sensation among cases when pain at day 1 and day 8

was compared ($p < 0.001$). Significant difference was also found among controls (p value 0.0156). When pain at day 3 and day 8 was compared between cases and controls, Wilcoxon matched pairs test showed significant difference (p value 0.0324). Karaca et al, observed that there was no statistically significant difference between Lichtenstein and PHS mesh repairs with regard to post-operative pain on days 1, 7 and 30.⁶ Also Sanjay et al in their study did not find any difference between the two groups.⁷ But Badkur et al, in their study observed that the percentage of patients with moderate to severe pain was more in the Lichtenstein group than in the PHS group (41.18% vs 15.15%) which was statistically significant.³ Our study is consistent with most of the literature and did not find any difference between the two groups in terms of post-operative pain.

Seroma formation was seen among 2 (6.67%) cases in comparison to 3 (10.0%) controls. Prolene hernia system is slightly better in preventing seroma formation in comparison to Lichtenstein's technique. However, this difference was not found statistically significant. (p value 0.644). Badkur et al in their study observed that 3 (9.1%) out of 33 patients in PHS group and 4 (11.8%) out of 34 patients in Lichtenstein group developed seroma, which is statistically not significant.³ Sanjay et al, in their study observed that there was a significantly higher rate of perioperative complications like seroma formation in the PHS group compared to Lichtenstein group.⁷ In the study done by Matyja et al, 1 (0.6%) out of 167 patients in the PHS group developed seroma, whereas 2 (0.6%) out of 301 patients in the Lichtenstein group developed seroma.⁸ Both the groups were comparable with a p value of 0.99. Most of the seromas will settle with conservative management. Those which are symptomatic and resistant to conservative management warrant evacuation. In our study, one patient had persistent seroma which needed evacuation.

Post-operative wound infection was seen among 1 (3.33%) cases and controls each. PHS is as better as Lichtenstein's technique in preventing post-operative wound infection. There was no difference among both techniques. All the wound infections were superficial, did not concern implanted material or fascia and were successfully cured with antibiotic coverage. Badkur et al, in their study observed that 1 (3%) out of 33 patients in PHS group and 1 (2.9%) out of 34 patients in Lichtenstein group developed wound infection, which is statistically not significant.³ Whereas, Karaca et al in their study did not notice any wound infection both PHS group and Lichtenstein group.⁶ Matyja et al, in their study observed that 6 (3.5%) out of 167 patients in the PHS group and 8 (2.6%) out of 301 patients in the Lichtenstein group developed wound infection.⁸

Chronic groin pain was seen among 2 (6.67%) cases and 3 (10.0%) controls. PHS is slightly better than Lichtenstein's technique in regard to chronic groin pain. There was no statistically significant difference among

both techniques (p value 0.644). With the incidence of recurrence being stabilized since the introduction of tension free repairs, the focus has somewhat shifted to the occurrence of chronic groin pain. We observed it to be an underrated problem in inguinal hernia repairs. Different case series report varied incidence of chronic groin pain and it is difficult to exactly pinpoint the cause for the same.^{3,8} We would like to state that chronic groin pain is an underrated and emerging problem in inguinal hernia repairs. It is important in this era to give a better quality of life for inguinal hernia patients. Larger prospective studies are needed in this regard to evaluate the exact incidence, possible mechanisms and possible treatment options.

Recurrence was seen neither among patients treated with Hernioplasty using PHS nor among patients treated with LTH. It may be a bit early to conclude that both the groups are comparable in terms of recurrence as it can occur many years following surgery. However, early results (5 months to 2 years of follow up) for recurrence are comparable in both the groups.

CONCLUSION

From this study we conclude that both mesh repair techniques, LTH and PHS have comparable short and long-term outcomes in terms of duration of surgical procedure; post-operative hospital admission; early complications like seroma and wound infection; and late complications like chronic groin pain and recurrence. PHS is a suitable alternative to time honored LTH in affordable patients with added advantage of strengthening the whole of myopectineal orifice, and virtually eliminating any risk of recurrence.

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